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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,234	08/08/2006	Hazem El-Refaey	BBD.P0022	1287

7590 09/25/2009  
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EXAMINER
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PESELEV, ELLI

ART UNIT	PAPER NUMBER
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1623

MAIL DATE	DELIVERY MODE
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09/25/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/563,234	EL-REFAEY, HAZEM	
	<b>Examiner</b>	<b>Art Unit</b>	
	Elli Peselev	1623	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 September 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 40-54 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 40-54 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 4, 2009 has been entered.

Claim 52 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 40-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kirschner et al (U.S. Patent No. 6,899,890) in combination with Herschler (U.S. Patent No. 4,997,823) and Kelly (WO 02/092097).

Kirschner et al disclose vaginal drug delivery (column 5, lines 34-44) suitable for delivery of therapeutic drugs. Kirschner et al also teach that that the therapeutically active drug or drugs may be any of those which are used for the treatment of vagina, including antibacterial agents (column 12, lines 62-65) such as azithromycin or metronidazole (column 13, lines 30-31). Kirschner et al further disclose a method of treating vaginal infection (column 14, lines 58-67). However, Kirschner et al do not

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disclose the administration of antibiotic in combination with prostaglandin. However, since an anti-infection composition comprising a combination of prostaglandin and an antibiotic was known in the art at the time the claimed invention was made as disclosed by Herschler (column 2, lines 13-60) and vaginal delivery of prostaglandins was known in the art as disclosed by Kelly, it would have been prima facie obvious at the time of the claimed invention to administer vaginally a combination of an antibiotic azithromycin in combination with prostaglandins for the treatment of infections.

Applicant's arguments filed September 4, 2009 have been fully considered but they are not persuasive.

Applicant contends that reference to azithromycin in Kirshner et al is limited to a passing mention in a long list of antibacterial agents. Applicant also contends that there is no teaching or suggestion in the cited prior art that azithromycin and prostaglandin can be administered vaginally for the treatment of pelvic infections. This argument has not been found since vaginal administration of both azithromycin and prostaglandin was known in the art at the time of the claimed invention. Further note that Kirschner et al disclose a vaginal drug delivery system suitable for administration of any therapeutic agent. Applicant further contends co-administration of antibiotic and prostaglandin is advantageous because of a synergistic effect. The data on pages 10-14 of the specification has been considered but has not been found persuasive. It is not clear from the data provided what amount of the active ingredient was administered. Further, the data is directed to a combination of azithromycin and misoprostol. However, none of

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the claims are limited to said combination i.e. the data provided is not commensurate with the full scope of the claimed invention

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Elli Peselev  
/Elli Peselev/  
Primary Examiner, Art Unit 1623